EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

April 25, 2017

Appeal No.: 17-0023-AA
FDA Case No: 2016-10322

Charles Seife
New York University
20 Cooper Square, 6th Floor
New York, NY 10003

Dear Mr. Seife:

This responds to your February 6, 2017, appeal of the Food and Drug Administration's (FDA) decision to deny expedited processing of your December 5, 2016, Freedom of Information Act (FOIA)[1] request and the constructive denial of your request. Your December 5, 2016, FOIA request sought six categories of records related to the FDA's September 19, 2016, approval of the drug eteplirsen, manufactured by Sarepta Therapeutics and marketed as Exondys 51.

In your December 5, 2016, FOIA request, you asked for expedited processing on the basis that "a compelling need" existed for the disclosure of the information you had requested. You further stated that you are a member of the news media, primarily engaged in disseminating information to the public, and that there is an urgent need to inform the public about the FDA's accelerated approval of eteplirsen, for reasons including to permit the public to understand the drug's "controversial approval process".

On December 21, 2016, the FDA denied your request for expedited processing, explaining that your request did not meet the FOIA's requirements of demonstrating a "compelling need" involving either an imminent threat to the life or physical safety of an individual or an urgency to inform the public about an actual or alleged Federal Government activity.

On February 6, 2017, you appealed the FDA's decision to deny your request for expedited processing. In your appeal letter, you stated that since your initial request, "the need for information related to the approval process for eteplirsen has only become more urgent, and delay in response 'would compromise a significant recognized interest.'" In support of your appeal, you provided additional reasons why there was an urgent need to obtain the information you had requested, including because "the review of eteplirsen more generally has become the prism through which the accelerated approval pathway is viewed", and because new evidence about eteplirsen could "influence the review process conducted by the European Medicines Agency ("EMA") and other international regulatory agencies". In addition to appealing the FDA's decision to deny your request for expedited processing, you also appealed the FDA's "constructive denial" of the request.

[1] 5 U.S.C. § 552

After conducting a thorough review of your appeal, I have decided to uphold the FDA's decision to deny your request for expedited processing and its decision to process your request in accordance with the agency's "first-in, first-out" policy. My reasoning for this appeal determination is described below.

Expedited Processing

The FOIA directs agencies to provide for expedited processing of FOIA requests "in cases in which the person requesting the records demonstrates a compelling need," and in other cases as determined by the agency.[2] Under the FOIA, a requester can show a "compelling need" in one of two ways: (1) by establishing that his or her failure to obtain the records quickly "could reasonably be expected to pose an imminent threat to the life or physical safety of an individual";[3] or, (2) if the requester is a "person primarily engaged in disseminating information," by demonstrating that an "urgency to inform the public concerning actual or alleged Federal government activity" exists.[4]

Similarly, the Department of Health and Human Services' (HHS) expedited processing regulation provides for the expedited processing of FOIA requests for persons who demonstrate "compelling need," as defined by the FOIA.[5]

In your initial request for expedited processing and your appeal letter, you attempted to demonstrate a "compelling need" on the basis that you are a "person primarily engaged in disseminating information" and that there is an "urgency to inform the public concerning" the FDA's September 19, 2016, approval of the drug eteplirsen.

For the purposes of this appeal, I do not need to address whether you are a "person primarily engaged in disseminating information" or that the subject of the requested records concerns an "actual or alleged government activity." The only question is whether your request for expedited processing adequately demonstrated an "urgency to inform the public".

When evaluating whether a requester has demonstrated an "urgency to inform", it is necessary to consider at least three factors: (1) whether the request concerns a matter of exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns federal government activity.[6]

In this case, you have failed to demonstrate an "urgency to inform" because your request does not concern "a matter of exigency to the public". Courts have routinely stated that in order to satisfy this standard for expedited processing, a "requester must show that the request concerns a 'breaking news story of general public interest.'"[7] Courts have also explained that there should be "widespread and intense media interest in the subject matter of the request in the time period immediately prior to when

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[2] 5 U.S.C. § 552(a)(6)(E)(i)
[3] 5 U.S.C. § 552(a)(6)(E)(v)(I)
[4] 5 U.S.C. § 552(a)(6)(E)(v)(II)
[5] 45 C.F.R. § 5.27(b).
[6] *Bloomberg, L.P. v. United States Food & Drug Admin.*, 500 F. Supp. 2d 371, 377 (S.D.N.Y. 2007) (quoting *Al-Fayed v. C.I.A.*, 254 F.3d, 310 (D.C. Cir. 2001).
[7] *Treatment Action Grp. v. FDA*, No. 15-cv-976, 2016 U.S. Dist. LEXIS 127877 at *29 (D. Conn. Sept. 20, 2016) (quoting *Wadelton v. Dep't of State*, 941 F. Supp. 2d 120, 123 (D.D.C. 2013)).

the request was made,"[8] meaning a request should concern recent events as of the time the request was made.[9] Moreover, courts have noted that it is not enough for a request to concern a topic that is newsworthy; the topic must be the subject of a currently unfolding story.[10]

Here, you made your request for expedited processing approximately two-and-a-half months after the FDA announced its approval of eteplirsen. In the past, a United States District Court has rejected a claim of an urgent need to inform the public about government activities where the activity took place two or more months before the request was made.[11] At the time you made your request for expedited processing, the topic of your request was not a "breaking news story" concerning recent events.

There was a steady decline in the amount of media attention concerning eteplirsen between the date the FDA approved the drug and the date of your request. A LexisNexis Advance general news search (filtering out articles with a high similarity) reveals that there were 296 articles containing the words "eteplirsen" or "Exondys 51" in the week after the FDA's approval of the drug (September 19, 2016 to September 26, 2016). On the other hand, conducting the same search for the week prior to your request (November 28, 2016 – December 5, 2016) yields just 12 articles. This represents a 96% decline in the number of articles referencing "eteplirsen" or "Exondys 51" and clearly indicates that there was not a widespread and intense media interest in the subject matter of your request in the time period immediately prior to when your request was made. It is also worth noting that some of the 12 articles mentioning "eteplirsen" or "Exondys 51" written in the week prior to your request do not even mention the FDA's approval of the drug or simply mention the drug in passing as an example of one of a few drugs that has received accelerated approval.

In addition, it should be noted that the FDA has already proactively posted more than 2,000 pages of records related to eteplirsen's approval on its website.[12] This includes information about the internal scientific dispute resolution process that was conducted as part of the drug's approval.[13] As a general matter, the FDA routinely makes available materials related to the approval of new drug applications on its website for the public's benefit.[14]

Finally, when considering granting expedited processing, it is necessary not to forget the interests of all requesters in having their requests treated equally, as well as the public interest in the integrity of the FOIA process. Because a decision to grant expedited processing of a FOIA request necessarily entails further delay for other requests, fairness demands that it be made only after ensuring it meets the standard for expedited processing set forth above. Since your request does not involve a topic that is the subject of a "breaking news story of general public interest", there is no "urgency to inform the public concerning actual or alleged Federal government activity" and your request for expedited processing is denied.

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[8] *Treatment Action Grp.*, 2016 U.S. Dist. LEXIS 127877 at *29 (quoting *Wadelton*, 941 F. Supp. 2d at 123).
[9] *Wadelton*, 941 F. Supp. 2d at 123.
[10] *Al-Fayed*, 254 F.3d at 310.
[11] *Treatment Action Grp.*, 2016 U.S. Dist. LEXIS 127877 at *30
[12] *See* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488_TOC.cfm; http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488_summary%20review_Redacted.pdf; http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/ucm478063.htm
[13] *See* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/206488_summary%20review_Redacted.pdf
[14] *See* https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm

Constructive Denial

The FOIA includes a general requirement that federal agencies make a determination on a request within 20 working days,[15] unless exceptional circumstances exist.[16] With respect to these exceptional circumstances, courts have repeatedly held that when an agency can show (1) a great number of requests and inadequate resources, and (2) good faith and due diligence in complying with requests by processing them in a first-in-first-out basis within tracks, the agency may take longer to process the FOIA request.

The FDA needs additional time to respond to your request because of exceptional circumstances. The FDA receives and processes a large number of FOIA requests every year. In Fiscal Year 2016, the FDA received more requests than it had received in any single year since Fiscal Year 2007. This trend continued during the time period that your initial request was received. In the first quarter of Fiscal Year 2017, the FDA received 2,706 requests. That represented a 28% increase in the number of requests it had received during the same time period just two years prior. Moreover, the FDA has been processing requests that are increasingly complex in nature each year. In Fiscal Year 2016, nearly 40% of the requests that the FDA processed were classified as complex. Over a three year period, the number of complex requests processed by the FDA has increased by 30%.

At the same time, the FDA has shown due diligence in processing FOIA requests on a first-in, first-out basis in as short a time as possible. In Fiscal Year 2016, the FDA reported its lowest number of backlogged requests – 2,248 – since agencies first began including this statistic in their Annual FOIA Reports in Fiscal Year 2008. Over the last two years, the FDA has reduced its backlog by 14% while it has experienced an increase in the number of requests it has received over the same time period.

Upon receipt, your request was assigned to the FDA's Center for Drug Evaluation and Research (CDER) and the Office of the Commissioner's Office of the Executive Secretariat (OES) and placed in the complex processing queue. The decision to place your request in the complex processing queue was based on the number of items requested and the types of records sought. Your FOIA request sought six different categories of records including three categories that contained multiple subparts. In order to process your request, the FDA will have to conduct a thorough search of multiple offices including the email files of several FDA officials, some of whom are no longer with the agency. If the FDA is able to locate records responsive to your request, it will have to conduct a line-by-line review of the material to determine whether it can be released to you, in full or in part. As a result, your request has been placed in the complex processing queue.

With that said, the FDA can further assist you with the processing of your request. If at any point in the FOIA process you need assistance with the processing of your request, you may contact the FDA's FOIA Public Liaison. This individual can assist you in reducing delays in the processing of your request, increasing transparency and understanding of the status of your request, and assisting to resolve any FOIA disputes. The FDA's FOIA Public Liaison can be reached using the following contact information:

Sarah Kotler, Director
Division of Freedom of Information, OES

[15] 5 U.S.C. § 552(a)(6)(A)(i)
[16] 5 U.S.C. § 552(a)(6)(C)(i)

U.S. Food & Drug Administration
5630 Fishers Lane
Room-1035
Rockville, MD 20857

Telephone: 301-796-8976
E-mail: Sarah.Kotler@fda.hhs.gov

You may also seek assistance from the HHS FOIA Public Liaison. This individual can be reached using the following contact information:

Michael Bell
HHS FOIA Public Liaison
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Telephone: (202) 260-0793
E-mail: HHS_FOIA_Public_Liaison@hhs.gov

Finally, you may seek assistance with the processing of your request from the Office of Government Information Services (OGIS). OGIS serves as the Federal FOIA ombudsman and assists requesters and agencies to prevent and resolve FOIA disputes through mediation. Using OGIS services does not affect your right to pursue litigation. You may contact OGIS in any of the following ways: Telephone: (202) 741-5770; Facsimile: (202) 741-5769; E-mail: ogis@nara.gov; or U. S. Mail at:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road – OGIS
College Park, MD 20740

This letter constitutes the final decision of the Department of your February 6, 2017 appeal. If you wish, you may seek judicial review in the district court of the United States in the district in which you reside or have your principal place of business, in which the agency records are located, or in the District of Columbia.

Sincerely,

Catherine Teti
Executive Officer
Deputy Agency Chief FOIA Officer